REMARKS

Claims 1-10 and 28-30 are pending. Claims 11-27 have been canceled without prejudice. Claims 1, 2 and 9 have been amended. Support for the amendments is found throughout the specification and are depicted in the drawings. Reconsideration of the rejection is respectfully requested.

Claims 1-10 and 28-30 were rejected under 35 USC 112, second paragraph as being indefinite by reciting "capable of" and claim 1 allegedly being incomplete for omitting essential steps. This rejection is respectfully traversed.

The examiner contends that "capable of" is not a positive limitation to an element. This rejection may be appropriate if one were claiming a machine or other device. However, these claims are methods and the capabilities of a composition are meaningful as to the method steps being performed using such a composition. The binding agents are compounds or compositions for which their capabilities are their primary distinguishing feature. Therefore, the use of "capable of" is appropriate and certainly not indefinite.

Also, the Examiner contends that how the particles are sedimented across a second slanted solid phase is omitted when they have already been sedimented across a first slanted solid phase. The rejection alleging an omitted step demonstrates that the examiner has not fully understood the invention. Looking at Figure 3a, one can readily see that particles (30) in upper chamber (1) sediment downward to the slanted bottom surface of the upper chamber (1). The particles are shown to be concentrated in Figure 3a at the end of the slanted bottom surface (a first slanted solid phase) as they pass through aperture (26) and are then sedimented in slanted chamber (10) across strip (34) (a second slanted solid phase). Therefore, it is possible for a single particle to sequentially sediment across both a first and a second slanted surface without a missing step.

Claims 1-10 and 28-30 were rejected under 35 USC 103 as being unpatentable over Suovaniemi in view of Anderson et al ('834). This rejection was discussed in the previous rejections and replies.

Suovaniemi describes an agglutination test where whether or not an analyte is present determines whether or not red blood cells agglutinate. Non-agglutinated red blood

cells settle to a slanted surface and stay on the slanted surface whereas larger agglutinated clumps roll/slide off the slanted surface. The presence or absence of agglutination may be easily measured by looking at the slanted surface and seeing if it is red or clear. It is the presence or absence of agglutination which is measured and from which particle identification is deduced. No further analysis for identification of the particle is performed in such a test.

Contrary to the Examiner's assertions, Suovaniemi does not perform a sedimentation step on a slanted surface followed by sedimenting on a second different slanted surface. Suovaniemi does not concentrate particles using a first slanted surface before having the particles contact a second surface for analysis. In Suovaniemi column 4, lines 4-12, a binding is mentioned in Suovaniemi (but never used) that is only one coating, not a portion and not multiple different specific binding agents located in different locations. Furthermore, Suovaniemi does not even teach a second slanted surface on which to attach the binding agents as claimed.

None of the differences are compensated for by Anderson et al who bands particles in a liquid region of a density gradient. There is no immobilized binding agent of any type in Anderson et al. Anderson et al is a concentrating technique, there is no identification of the type of particle in Anderson et al in the vessel.

Anderson et al's concentration method, which uses a density gradient, is inoperable for agglutination type assays because a band does not distinguish clumps from single cells. While the Examiner contends it obvious to first concentrate particles by the Anderson et al concentration method, this teaches against Suovaniemi who needs the particles to be dispersed over a large slanted surface to detect non-agglutination. While concentration does increase binding efficiency, using concentration in Suovaniemi defeats the purpose where one wishes binding of unagglutinated particles to form maximum spread on the surface. Again note that Anderson et al has no binding to any surface and even teaches coating the surfaces to **prevent** binding. See Anderson et al claim 6 "...in which the inner surfaces are coated with adhering polymer to prevent adsorption of biological particles."

On page 5 lines 5-6, the Examiner states that immobilization of the particles in Anderson et al would be desirable to achieve greater binding efficiency. This assertion is

completely contrary to the teachings in Anderson et al to take positive steps to avoid any binding of the particles.

As a separate issue, the antigens or antibodies that are mentioned in Suovaniemi don't actually bind the particles but rather only a complex or a compound not found on a particle. Column 4, lines 4-12 states that "...it is easy to wash free red corpuscles or any other particles off from the cuvette so that only the agglutinated complex is not removed by washing." This indicates that the particles are not bound to the surface.

Furthermore, it is readily apparent that only one type of binding agent would be on the surface of Suovaniemi and clearly different binding agents at different locations on the surface are not even remotely suggested.

In response to previous arguments, the Examiner contends on page 5 point 10 that Suovaniemi does have cells concentrated on the slanted solid phase. This statement misses the point. Claim 1 recites that the **second** slanted solid phase has immobilized binding agents and Claim 1 recites detecting particles bound on the **second** slanted solid phase. Suovaniemi does not teach a **second** slanted solid phase at all and therefore does not have cells concentrated on the **second** slanted solid phase.

In response to previous arguments, the Examiner contends on page 5, point 11 that Suovaniemi does not require the "cells me spread over the entire surface". It appears the Examiner intends to state that Suovaniemi does not require the bound complexes to be spread over the entire surface. The lack of a specifically stated requirement does not imply that Suovaniemi intends for specific different binding agents be immobilized at specific different areas on the slanted surface. Even then, at best Suovaniemi would have their "binding agent" on the wrong slanted solid phase.

In the final rejection on page 6, lines 6-8, the Examiner states that there is no basis for the assertion that Suovaniemi would be inoperable by adding a density gradient. If one used a trivially small density gradient, one might agree but that is not what is taught by the references. The density gradients taught by Anderson et al band particles in one discrete area away from the bottom for easy collection. Unless the red corpuscles in Suovaniemi contact the slanted surface and either roll/slide off or not, one does not know whether agglutination has taken place. Therefore, by keeping the red corpuscles suspended above

the solid phase, one does not have a result for whether or not agglutination has occurred and thus one does not have a complete operable agglutination test.

In the final rejection page 6 point 13, the Examiner argues that the claims do not recite certain features. It should be noted that claim 30 does recite that "said sedimentation path of a single particle passes through said first slanted solid phase and said second slanted solid phase."

In the final rejection page 6 point 14, the Examiner argues that Suovaniemi does not require the particles to be spread out. If they are not spread out then one does not have one of the two different possible results from the agglutination test and therefore all tests would give the same result. Furthermore, the last two lines state "Anderson represents the second step in which the particles are bound by their receptor on another solid phase to allow for detection." This is not correct. Anderson et al do not bind the particles to a solid phase at all but rather bands the particles in liquid as stated twice above.

In the final rejection page 6 point 14, the Examiner urges that Anderson et al teach reagents contained within small zones. However, these zones are in suspension in a density gradient, not immobilized on a solid phase. A liquid zone is not an immobilized region. This is especially true when Anderson et al specifically teach (and even claim) that one prevent immobilization. Therefore, these two features are not interchangeable with each other.

The Examiner contends that the claims do not require immobilization on a small part of the solid phase. A part is not a whole. A Suovaniemi teaching to coat "the bottom of a cuvette" is the entire surface, not a distinct **part** of a surface as claimed. Further, this cannot be possible with the recitations in claim 3 where one has at least two different regions on the solid phase each with different binding agents immobilized thereon.

Contrary to the Examiner's assertions on page 7, lines 4, 6, 8, 11, 12, and other locations, use of plural immobilized binding agents are not taught by either reference.

As for adding a stain as a binding agent, claim 9 recites that the binding agent is a specific binding agent. Since claim 10 recites using a stain separately, it should have been clear that applicants always intended the added binding agent to be a specific binding agent, such as an antibody. Claim 9 has been amended to recite this.

Since certain features and steps of the presently claimed invention are not taught nor suggested, the claimed rejection over obviousness should be withdrawn. Furthermore as no possible operable combination of the references suggests the claimed invention, this rejection should be withdrawn.

CONCLUSIONS

In view of the amendments and comments above, the rejections have been overcome. Reconsideration, withdrawal of the rejections and early indication of allowance are respectfully requested. If any other issues remain, the examiner is encouraged to call the undersigned for prompt resolution of such matters.

If needed, applicants petition for an extension of time under the provisions of 37 CFR 1.136(a) for sufficient time to accept this response. The commissioner hereby is authorized to charge payment of any fees under 37 CFR § 1.17, which may become due in connection with the instant application or credit any overpayment to Deposit Account No.500933.

Respectfully submitted,

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